

107



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,572	06/12/2001	Arlene I. Ramsingh	0189-2001	4742

26694 7590 06/03/2004

VENABLE, BAETJER, HOWARD AND CIVILETTI, LLP
 P.O. BOX 34385
 WASHINGTON, DC 20043-9998

EXAMINER

CHEN, STACY BROWN

ART UNIT	PAPER NUMBER
----------	--------------

1648

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/879,572	Applicant(s) RAMSINGH ET AL.	
	Examiner Stacy B Chen	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-15,17-28,30-36 and 54-72 is/are pending in the application.
- 4a) Of the above claim(s) 2,19 and 54-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6-15,17,18,20-28 and 30-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This application has been transferred to Examiner Stacy Chen of Art Unit 1648.
Applicant's amendment, filed February 27, 2004, is acknowledged and entered. Claims 1-4, 6-15, 17-28, 30-36 and 54-72 are pending. Claims 1, 3, 4, 6-15, 17-18, 20-28 and 30-36 are examined on the merits. Claims 2, 19 and 54-72 are withdrawn from consideration, being drawn to non-elected inventions.
2. The rejection of claims 1, 3, 4, 18 and 20-26 under 35 U.S.C. 102(b) as anticipated by Caggana *et al.* (*J. Virol.* 1993, 67:4797-4803) is withdrawn in view of Applicant's amendment. However, Applicant's amendment incorporates new subject matter into the claims that is not disclosed in the specification (see rejection under 35 U.S.C. 112, first paragraph, below).
3. The rejection of claims 1, 3-6, 13-15, 17, 18 20-23 and 28 is withdrawn in view of Applicant's arguments and the second declaration of Arlene I. Ramsingh filed February 27, 2004, which has been considered.
 - Points 5 and 6 discuss the differences between "replacement" and "insertion" vector technology. Ramsingh distinguishes the instant claims from the Caggana reference by showing that Caggana's vector used replacement technology, while the instant claims use insertion technology. In response, Claims 1 and 3 do not recite any limitation about insertion, as in claim 4, for example.
 - Points 7 and 8 discuss the new claim limitation "non-coxsackievirus", which distinguishes over the Caggana reference. Ramsingh also argues that CB4/CB4-V chimeras do not include what are commonly accepted as "heterologous" sequences. In response, the specification fails to exclude chimerics and does not give any guidance on

Art Unit: 1648

what degree of homology is required to qualify as heterologous or homologous. The claims are not supported by the new limitation “non-coxsackievirus”.

- Point 9 discusses the differences between CVB-3 and CVB-4 serotypes. Ramsingh asserts that there would be no expectation of success that an immunogenic virion or viral vector construct used as a vaccine, for example, based on one virus would result in a similar level of immunity as a vaccine based on the other virus. In response, Applicant is arguing about the protective capabilities of a coxsackievirus vaccine, however, the claims are drawn to a virus vector. If one of ordinary skill were constructing a vector, one would not be looking at the protective capabilities of the vector itself, but of the gene of interest delivered by the vector. In the present case, the vector is a coxsackievirus virion, and the gene of interest is a non-coxsackievirus gene.
- Point 10 discusses basic immunological concepts without relating to the issues at hand.
- Point 11 discusses the differences between Tracy’s vector, which does not disclose a heterologous polypeptide fused to a capsid protein of the virion. Applicant also attempts to incorporate references that are not of record. These references have not and will not be considered by the examiner unless submitted in a proper information disclosure statement. In response to the argument regarding the fusion aspect of Applicant’s invention, now recited in claim 1, the Office recognizes the distinction between Tracy and the instant invention.

Art Unit: 1648

Claim Rejections - 35 USC § 112

4. Claims 1, 3, 4, 6-15, 17-18, 20-28 and 30-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 and all depending claims recite the new limitation, “non-coxsackievirus”, which is not supported by the specification. While the specification gives examples of epitopes of interest that are not coxsackievirus (page 19), the specification does not exclude coxsackievirus chimerics. The specification defines “heterologous nucleic acid” as “any nucleic acid which is not otherwise naturally present in the genome of the virus at the position at which it is inserted”, page 12, lines 30-34. This definition clearly encompasses nucleic acid that is from another species of the same virus. Therefore, the claims contain new subject matter not supported by the specification.

Conclusion

5. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

Art Unit: 1648

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SPC

Stacy B. Chen
May 20, 2004

James C. Housel
JAMES HOUSEL 6/1/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600